

93. (new) The apparatus defined in claim 91, wherein said backup or reserve supply container is attached to a portion of the apparatus.

94. (new) The apparatus defined in claim 76, and further comprising humidity sensing means positioned in the chamber in the flow path of the gas stream.

95. (new) The apparatus defined in claim 94, and further comprising heating means disposed within the chamber for heating the gas.

96. (new) The apparatus defined in claim 95, and further comprising:

- a) temperature sensing means disposed within the chamber for sensing the temperature of the gas in the chamber; and
- b) control means connected to the temperature sensing means and to the heating means and responsive to the temperature sensing means to control electrical power to the heating means so as to regulate the amount of heat applied by the heating means to the gas within the chamber.

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REMARKS

Claims 1-33 were originally pending in the present application. Of these, claims 1-24 were identified by the Examiner as drawn to an apparatus for treating a gas with an agent, classified in class 604, subclass 83, and claims 25-33 were identified as drawn to a method for treating a gas for delivery to an animal, classified in class 604, subclass 500.

By this response, the undersigned attorney of record hereby affirms the provisional election made with traverse to prosecute the invention of claims 1-24 that was made via telephone by previous counsel of record on February 9, 2001. The undersigned attorney of record also acknowledges the withdrawal by the Examiner of claims 25-33 from further consideration. However, as previously indicated, claims 1-24 have been cancelled, and new claims 34-96 have been submitted. Therefore, claims 34- 96 are currently pending in the present application. For the reasons discussed below, these claims are believed allowable.

## CLAIM REJECTIONS

### 35 USC § 102

The Examiner has rejected claims 1-6, 17 and 18 as being anticipated by U.S. Patent No. 5,411,474 ('474). Even though these claims have been cancelled, Applicant respectfully submits that the instant application is not anticipated by ('474) for the reasons that follow.

The ('474) patent teaches an apparatus for heating, humidifying and filtering insufflation gas prior to the delivery of the gas to the body cavity of a patient. This apparatus is comprised of a housing having one chamber in which a volume of water is placed in “flow communication with the gas as it travels through the chamber,” thereby achieving humidification of the gas (column 12, lines 21-22). The heating means is “disposed within or around the water” (column 12, lines 23-24). In short, the ('474) patent teaches treatment of a gas with water and heat only.

Moreover, the ('474) patent does not contemplate treatment of the gas with any agent other than water for delivery to a patient, nor does it contemplate an embodiment having more than one chamber for treating the gas with multiple agents in addition to the water. These two aspects are taught by the instant application to further improve upon and advance the apparatus and methods taught by the ('474) patent for gas conditioning (page 2, line 1). The invention is to be used for the delivery of “any material that can be carried by the flow of gas into a body cavity or onto a surface for therapeutic or diagnostic purposes...” (page 4, lines 21-22). The ('474) patent was issued during a period of recognition by those skilled in the art of the delivery of gas into a body cavity that warming of the gas before delivery appeared to significantly influence the patient’s amount of post-laparoscopic pain (Korell, M., et al., Pain Intensity Following Laparoscopy, Surgical Laparoscopy & Endoscopy, (1996) Vol. 6, No. 5, pp. 375-379) and that humidification of the gas might also influence the patient’s core body

temperature to avoid post-operative hypothermia (Bessell, J.R., et al., Hypothermia Induced By Laparoscopic Insufflation, 1995, Surgical Endoscopy, (1995) 9: 791-796).

Applicants discovered that the gas could be conditioned with other “agents,” *i.e.*, organic and/or inorganic substances, so that the agents may be administered to the patient in the gas. The use of humidifying solutions and multiple agents, in turn, led to the need for alternative supply containers. The ('474) patent does not teach the use of one or more separate bags filled with a desired humidifying solution, or agent that may be placed within the housing, such that the agent may be “wicked off” into the flowing gas stream (page 11, lines 22-29 through page 12, line 12), or attached to the exterior of the housing (page 12, lines 23-25). Nor does it teach the use of any other alternative container for supply and delivery of agents to the gas stream, such as tubing or an inkjet printhead, such as is proposed by the instant application.

Further, the fact that the aforementioned humidifying solutions or agents have different, and most probably, more complex molecular structures than water, necessitated the development of a gas treatment apparatus that would evenly and thoroughly distribute the agents into the gas stream. For example, the embodiments of the inventive apparatus proposing delivery of an agent through a restrictive orifice or hole to form a bead of agent that may be wicked off into the gas stream actively deliver the agent into the stream, as opposed to simply passing the gas through a humidification bed such as taught by the ('474) patent. Further, use of an inkjet printhead to create vapor bubbles of the agent to be delivered into the gas stream certainly demonstrates the active delivery of an agent into a gas stream, as well as an element that is wholly novel to the inventive apparatus (page 14, line 17 through page 15, line 16).

In light of the fact that the ('474) patent does not even contemplate treatment of the gas to be delivered to a patient with any substance other than water, the need to include alternative containers for holding the substances was nonexistent. The alternative

embodiments of the apparatus proposed by the instant application cannot be accomplished by modification of the apparatus taught by the ('474) patent.

Finally, the Applicant respectfully points out that the apparatus taught by the ('474) patent does not include a pressurizer/humidifier element, as suggested by the Examiner. Pressurization of the gas delivered by the apparatus taught by the ('474) patent is regulated by the insufflator that is attached to the inventive apparatus (column 6, lines 27-28).

For the foregoing reasons, the Applicant respectfully submits that the apparatus proposed by the instant application is not anticipated by the apparatus taught by the ('474) patent.

#### 35 USC § 103

The Examiner has rejected claims 8, 10, 11, 13, 14, and 21-24 as being unpatentable over Ott, et al. ('474) in view of Nishino, et al. on obviousness grounds. The Applicant respectfully submits that combination of the humidity sensing device taught by Nishino, et al. with the apparatus taught by the ('474) patent was not obvious to one skilled in the art at the time of invention. As previously discussed, at the time of the ('474) patent, and after, studies were being performed to explore the hypothesis that heating and humidification of gas used for insufflation might be effective in reducing such conditions as post-laparoscopic pain and hypothermia. As recognized by Ott, et al., attention had just been turned to the possibility that insufflation gases used to create a pneumoperitoneum for laparoscopic surgical procedures should be heated, humidified and filtered (column 1, lines 20-25).

As humidification of insufflation gas as become more widely used, particular problems have been recognized with the procedure. For example, the humidification system should be set up such that a constant supply of water may be available to humidify the insufflation gas throughout the entire length of the laparoscopic procedure. The problem posed by this seemingly simple statement is that it is impossible for a

practitioner to know how much gas will actually be used during any procedure. The practitioner has no control over the amount of gas that is used other than the setting of the flow rate on the insufflator that delivers the gas from the gas source.

Further, a number of uncontrollable variables, such leakage of the gas through incisions, changes in surgical technique in response to a patient's anatomy, and/or the occurrence of unexpected complications during the surgery, directly affect the amount of gas that is actually required during the entire duration of a procedure.

Given that it is impossible to predetermine the amount of gas that may be required to complete a procedure, it is likewise impossible to predetermine the amount of water (or other humidifying solution) which may be required to humidify the gas used throughout the procedure. As humidification of gas used during laparoscopic procedures became a more widely-used practice, practitioners became increasingly aware of these problems. The Applicant proposed the addition of a humidity sensing and monitoring means in the instant application and in the parent application (U.S. Application No. 09/081,186, filed May 19, 1998, "Method and Apparatus for Conditioning Gas for Medical Procedures Having Humidity Monitoring and Recharge Alert," now Patent No. 6,068,609, issued May 30, 2000) as a partial solution to the problems. It is projected that the humidification sensing and monitoring means will be used to monitor the percentage of relative humidity of the gas attained after treatment and to alert the practitioner to a detected drop in the relative humidity, signaling a need for replenishment of the water or other humidifying solution. With respect to the inventive apparatus, the humidification sensing and monitoring means would also alert a practitioner to completion of the delivery of a liquid agent.

The remaining portion of the solution was the proposal of an external reservoir/bag member. Inclusion of this element allows a practitioner to have the external reservoir/bag member in order to ensure that a supply of water (or other humidifying solution) is available for humidification of gas used during an entire procedure. The fact

that it may be directly connected to the apparatus eliminates a need for inclusion of elements such as the humidity sensing and monitoring means. It also enables a practitioner to add an agent to be delivered to the patient at any point during a procedure by connecting the supply bag of the agent to the exterior of the apparatus. Thus, for example, if a practitioner discovers, during the course of a laparoscopic procedure, a previously undetected abscess, an antibiotic solution could be prepared and administered directly to the patient via the gas flow.

In addition, it is contemplated that the external reservoir/bag member will simplify the construction of the inventive apparatus. That is, by creating the ability to directly connect the external reservoir/bag member to the apparatus to ensure that ample agent is available for an entire procedure, the need for certain parts, such as humidity and temperature sensing and monitoring features, or the recharge alert, may be eliminated in some embodiments of the apparatus (page 18, lines 1-15).

Finally, with respect to the Examiner's rejection of claims 1-6, 17, 18 and 21-24 as being unpatentable over Ott, et al. and Nishino, et al. (U.S. Patent No. 4,276,128), and further in view of Absten (U.S. Patent No. 5,246,419), Applicant respectfully submits that it is specified within the instant application that the relative humidity of the gas in the gas treater and exiting the chamber is measured by a humidity sensor (page 22, line 21-22). The operation of the humidity sensor is further specified by the instant application (page 22, lines 22-29, and page 23, lines 1-6).

Applicant respectfully disagrees with the Examiner's assessment of the teachings of Absten, et al. Particularly, Absten, et al. teaches an apparatus for supplying insufflation gas at high flow rates during laparoscopic surgery (column 2, line 43-45). Absten also teaches that one element of the typical embodiment of said apparatus would include a pressure sensor, *i.e.*, at least one pressure gauge, connected to a microprocessor to automatically reduce the gas flow when a predetermined limit is exceeded (column 5,

lines 36-39). Thus, Absten describes an apparatus including a microcontroller used to measure gas pressure.

Absten does not, however, teach the use of the microprocessor for any other purpose other than to measure the pressure of the insufflation gas. Likewise, Absten does not describe with specificity the exact operation of the microprocessor in monitoring the gas pressure levels. It is not stated, nor even suggested by Absten, that it would be within the capability of the microprocessor included in the apparatus to measure the relative humidity of insufflation gas. This is true despite the fact that Absten teaches humidification of the gas before delivery to the patient (column 3, lines 4-6). It does not appear that it was at all obvious, even to Absten, that his own microprocessor could be used to monitor humidity levels in treated gas. It is therefore illogical to suggest that it would have been obvious to anyone else of ordinary skill in the art.

There is therefore scant support for the Examiner's assumption that the microcontroller or microprocessor component of the apparatus taught by Absten, et al., would be capable of monitoring humidity levels of gas. Moreover, in consideration of the fact that it was only recently proposed by those skilled in the art that humidification of the insufflation gas may be of any therapeutic value, it is unreasonable to suggest that monitoring of the humidity was an obvious concept.

#### Double Patenting

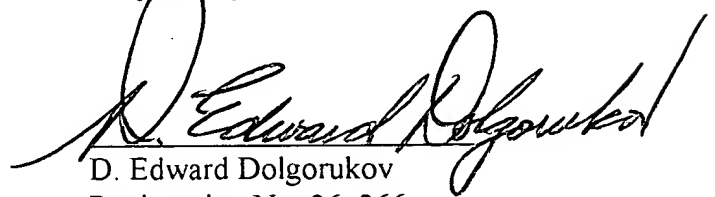
The Examiner has rejected claims 1-6, 17, 18, and 21-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,411,474 and over claims 1-42 of U.S. Patent No. 6,068,609. Applicant has previously discussed how the aspects of the instant inventive apparatus render it substantially dissimilar from the apparatus taught by claims 1-15 of Patent No. 5,411,474. It is also substantially dissimilar from the apparatus taught by claims 1-42 of U.S. Patent No. 6,068,609 for the same reasons.



Patent No 6,068,609 teaches an apparatus that, like that taught by Patent No. 5,411,474, is used to heat, humidify, and filter insufflation gas, but also added the additional aspects of being able to monitor and control the levels of heat and humidity that are added to the gas. In fact, Patent No. 5,411,474 was incorporated in its entirety by reference into Patent No. 6,068,609 (column 1, lines 58-60). Although Patent No. 6,068,609 improves upon the apparatus taught by Patent No. 5,411,474 by adding the capability to monitor the humidification level and recharge the supply of liquid being used for humidification of the gas, it does not teach treatment of the gas with one or more agents in addition to humidification. It also does not teach an apparatus that may be changed depending upon the identity and number of agents used to treat a gas. The inventive apparatus allows a user to add several agents to a gas, even mid-procedure if necessary, which was heretofore not possible. Compared to prior inventions, which were intended to improve the quality of the gas to decrease deleterious effects on the patient, the instant invention is used to directly deliver agents that will be therapeutically beneficial to the patient.

For these reasons, the claims now pending in the instant application set forth an apparatus that is patentably distinct from either Patent No. 5,411,474 or 6,068,609 and therefore traverses the requirement for a terminal disclaimer.

Respectfully submitted,

  
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